REMARKS

Status of the Claims

Claims 1-9 and 15 are pending. Claims 1-5 are rejected. Claims 6 and 7 are objected to. Claims 8, 9 and 15 are allowed. Claims 1, 7 and 9 are amended. Claim 6 is canceled due to being incorporated into claim 1. No new matter has been added. Reconsideration of the pending claims is respectfully requested.

Claim amendments

Claim 1 is amended to overcome rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a), as discussed *infra*. Claims 7 and 9 are amended to correct grammar. Claim 6 is canceled and Claim 7 is amended to overcome objections to the claim. No new matter is added in any claim amendment.

The 35 U.S.C. §102 Rejection

Claims 1 and 3-5 are rejected under 35 U.S.C. §102(b) as being anticipated by **Harper *et al*** (U.S. Patent No. 5,714,516). This rejection is respectfully traversed.

The Examiner in his previous Office Action states that **Harper *et al*** teaches a method of treating a virus infection in an individual comprising administering to such an individual an effective amount of 2-bromopalmitic acid or salts thereof as well as compositions which comprise 2-bromopalmitic acid or salts thereof and a pharmaceutically acceptable carrier (Abstract; col. 2, ll. 26; col. 2, ll. 63 to col. 3, ll. 10). The Examiner also states that the biochemical functions as recited in claims 1 and 3-5 are deemed inherent in the prior art method because the same host is administered the same active agent. Applicant respectfully disagrees.

Harper *et al.* teaches methods of treating herpes virus infections by administering hydroxy or bromine derivatives of myristic acid, including 2-bromopalmitate (Abstract; col. 1, ll. 47 to col. 2, ll. 37). **Harper *et al.*** demonstrates that 2-hydroxymyristic acid and 2-bromopalmitic acid could inhibit plaque formation by Varicella zoster virus (VZV) in Mewo monolayers *in vitro* (col 4, ll. 27 to col. 5, ll. 29).

Applicants' invention as recited in amended claim 1 incorporates the limitation of claim 6 and is drawn to a method of inhibiting Fyn/Lck fatty acylation and protein palmitoylation in a cell

in an individual having an autoimmune disease. Administration of 2-bromopalmitate inhibits Fyn/Lck fatty acylation thereby inhibiting subsequent T-cell receptor mediated signaling events. At a minimum, **Harper** *et al.* cannot anticipate Applicants' invention because the reference does not teach that the individual has an autoimmune disease. **Harper** *et al.* specifically teaches, as a first demonstration, the effect of the myristic acid analogs, including 2-bromopalmitate, against non-retroviral infections, such as herpes virus infections.

Absent teachings, either expressly or inherently, of inhibiting Fyn/Lck fatty acylation and protein palmitoylation in a cell in an individual having an autoimmune disease, **Harper** *et al.* does not anticipate claims 1 and 3-5, as amended. Thus, **Harper** *et al.* is not prior art under 35 U.S.C. 102(b). Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1 and 3-5 under 35 U.S.C. §102(b) be withdrawn.

The 35 U.S.C. §103(a) Rejection

Claim 2 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Harper *et al*** (U.S. Patent No. 5,714,516). This rejection is respectfully traversed.

The Examiner states in his previous Office Action that **Harper** *et al* fails to highlight the dosages and the conditions the host suffer. The Examiner also states that it would be obvious for the skilled artisan to determine the optimum dosage to provide the most effective therapy possible. Applicant respectfully disagrees.

Harper *et al* has been discussed *supra*. Applicants' invention is as discussed *supra*. No suggestion is present in **Harper** *et al.* that 2-bromopalmitate would have any effect on an autoimmune disease, particularly in inhibiting Fyn/Lck fatty acylation and protein palmitoylation in a cell in an individual with an autoimmune disease. One of ordinary skill in the art could not translate the effect of myristic acid analogs in reducing *in vitro* plaque formation by herpes viruses demonstrated in **Harper** *et al.* to a motivation to administer 2-bromopalmitate to an individual having an autoimmune disease to inhibit Fyn/Lck fatty acylation. A herpes viral infection is significantly different from an autoimmune disease with different etiologies, symptoms and progressive states.

Nor, from the disclosure in **Harper** *et al.*, would a skilled artisan find a reasonable expectation of success in inhibiting Fyn/Lck fatty acylation and protein palmitoylation and subsequent T-cell receptor mediated signaling events in an autoimmune disease. As stated *supra*, Fyn/Lck proteins are T-cell proteins, viruses do not have Fyn/Lck proteins and no T-cell component is present in the *in vitro* plaque assays presented in **Harper** *et al.* Any reasonable expectation of success is only found in Applicants' specification, as discussed *supra*. At best, one of ordinary skill in the art merely would be trying and it is well known that "obvious to try" is not the standard under 35 U.S.C. 103(a). Thus, amended claim 1 is both novel and non-obvious over **Harper** *et al.*

Claim 2 depends from amended independent claim 1 which further limits the dose of 2-bromopalmitate. If amended independent claim 1 is not obvious over **Harper** *et al.*, then the inclusion of one of the dependent claims cannot render Applicants' invention obvious over **Harper** *et al.*

Thus, Applicants submit that, lacking a teaching or suggestion of all the elements of the claimed invention and a reasonable expectation of success not found in Applicants'

disclosure, obviousness has not been established. Therefore, the invention was not obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, in view of the amendments and arguments presented herein, Applicants request that the rejection of claim 2 under 35 U.S.C. §103(a) be withdrawn.

Claim Objection

Claims 6 and 7 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance. Claim 6 is being incorporated into independent claim 1 and thereby being canceled, as helpfully suggested by the Examiner. Claim 7 is amended to correct grammar and dependency. The above amendment and cancellation of the claims overcome the claim objection. No new matter has been added.

This is intended to be a complete response to the Final Office Action mailed November 01, 2004. Applicant submits that the pending claims are in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicant believes no fees are due, however, if this in error, please debit any

fees due from Deposit Account 07-1185 on which Applicant's counsel is allowed to draw.

Respectfully submitted,

Date: Nov 19, 2004

Benjamin Aaron Adler, Ph.D.,J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391 (tel.)
(713) 270-5361 (fax)
badler1@houston.rr.com